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Counsel for Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Richard C. DiVerniero, John Catalano, M.D., M.D., and Richard Strauss, M.D.

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

All New Jersey Cases

MDL No. 2419
Docket No. 1:13-md-2419 (RWZ)

PREMIER ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF SOUTHERN NEW JERSEY, LLC, ET. AL'S MEMORANDUM IN OPPOSITION TO INSPIRA MEDICAL CENTER'S MOTION FOR PROTECTIVE ORDER Dkt. [2000]

Preliminary Statement

On or about May 15, 2015 Counsel for Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D. (hereinafter “Premier Defendants” or “Premier”) served a notice of Deposition to take the depositions of Joe Alessandrini and a corporate designee of Inspira Medical Center, Inc and Inspira Health System, Inc (Hereinafter “Inspira”) to address to a number of topics outlined therein (Dkt No.: 1861). Joe Alessandrini is the chief Pharmacist at Inspira Medical Center. Inspira is named in 21 of the 56 cases pending against Premier and in those cases Inspira’s Pharmacy ordered preservative free MPA from NECC and approved NECC as a vendor. This matter comes before the Court by way of a motion for protective order filed by the settled defendant, Inspira Medical Center [Dkt. No.: 2000]. This motion was preceded by a meet and confer by and between attorneys for Inspira and Premier. This meet and confer took place via telephone on June 10, 2015.

Essentially, Inspira has taken the position both during the meet and confer and in their motion papers that their contribution to the bankruptcy estate entitles them to immunity from discovery requests, subpoenas, notices of deposition and any participation in all discovery, whatsoever. In addition and perhaps in the alternative, Inspira is requesting to delay discovery until after the Bellwether Cases are selected and then argues that because no “Inspira case” will be selected discovery will become irrelevant shielding themselves from discovery in any event. Finally, Inspira balks at the request for deposition testimony and documents claiming privilege, irrelevance, violation of court order and other reasons.

The Premier Defendants now respond by identifying the many reasons why the discovery requests are not barred by the various orders of this Court and/or the Bankruptcy Court, how the discovery is relevant to Premier's Defenses. This includes not only the comparative fault defenses but why the request to delay the depositions is unreasonable. Finally, although asserted, Inspira has not substantiated a claimed of privilege to any of the requested discovery.

Legal Argument

I. **The Discovery Sought Against Inspira Is Common To Each And Every Case Filed And Pending Against Premier**

Inspira Medical center is located within blocks of Premier's Surgery Center and Premier's defendant doctors injected patients with NECC's MPA at both facilities. Years before the outbreak Premier Doctors were injecting patients with preservative free MPA compounded by NECC. The doctors were injecting these patients at Inspira Medical Center (Formerly South Jersey Healthcare) with NECC MPA, which Inspira purchased, approved and stored. In 2009 the doctors at Premier made arrangement to create and open a surgery center. In that process the Premier Defendants chose NECC to provide them with their preservative free MPA after Inspira's recommendation. Therefore, in 2012 Premier Doctors were injecting preservative free MPA compounded by NECC in Inspira Hospital's operating rooms and also in a surgical suite at Premier's free standing surgery center on varying days of the week depending on scheduling.

When MPA was injected at Inspira the drug was approved by Inspira, ordered by Inspira employees, using Inspira policies (written and unwritten), delivered to Inspira and stored at Inspira. After the outbreak, patients brought suit against Premier and their doctors for injections with tainted NECC, MPA that they received at both Inspira by Premier Doctors and at Premier's

own facility, also injected by Premier's doctors. Inspira ultimately entered into mediation and settled their differences by depositing \$16million into the bankruptcy estate.

Moving defendants argue that Premier has their own policies, procedures, consultants and management company for the vetting, selecting and approval of the use of NECC MPA. This statement is not accurate. The testimony of Michele Cassidy is clear. Ms. Cassidy is the administrator of Premier's Surgery Center and she testified that in 2009 when it came time for Premier's Surgery Center to decide from whom compounded MPA was to be purchased, Premier went to the hospital, in particular the Hospital's Pharmacy to inquire. Premier also sought the advice of Dr. Mitros, an anesthesiologist from Inspira at the time. In response to her inquiry Inspira recommended NECC.

To state that Premier independently vetted NECC without including the information obtained from Inspira during that vetting process is telling only half the story. The vetting process included, to a large degree, the Premier Doctors' years of experience using NECC MPA at Inspira while performing injections at Inspira. There was no process or procedure in place in 2009 before the Premier Surgical Center was opened. The vetting process included the recommendation from Inspira. Premier's due diligence included relying on the recommendation of Inspira and all of the knowledge and experience Inspira brought with that recommendation. According to F.R.C.P. 26 all of the above information is completely discoverable and relevant to 100% of the Premier cases whether Inspira is a party to those cases or not.

Moreover, for those cases were the injections occurred at Inspira, any information about the ordering process and decision to use NECC is highly relevant to show that the decision was Inspira's to make and not Premier's. When Premier must prove that the responsibility for ordering the preservative free MPA was Inspira's and not Premier's the requested discovery will

be absolutely necessary and admissible to such a defense. Without the necessary discovery, Premier will be prejudiced significantly by being left without the ability to apportion fault. Particularly so in cases where the injections occurred at Inspira and where Inspira unquestionably made the decision to order preservative free MPA from NECC.

II. Whether Classified As A Party, Settling Party Or Non-Party, Inspira Is Not Immune From Discovery.

Each and every case against the Premier Defendants implicates the collaboration between Premier and Inspira. Furthermore, 21 of the 56 cases pending against Premier occurred at Inspira using NECC products ordered by Inspira. The moving party makes the argument that these cases will never be chosen as Bellwether Cases or at least depositions should be stayed until the Bellwether process is complete. Reliance on such arguments is misguided and should not persuade this Court. If an entire cross section of cases will never be brought before a Jury then the logical end result should be dismissal and not discovery delays.

First, regardless of whether or not Premier is a defendant or once was a defendant in even one of the pending cases, discovery is allowed. There cannot be a dispute that the Premier Defendants are entitled to conduct the depositions of the Inspira representatives. Under Federal Rule of Civil Procedure 26(b)(1):

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense -- including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action.

See also, Fed. R. Civ. P. 30 ("A party may, by oral questions, depose any person, including a party ..."). Inspira, despite the assertions in its submission, possesses information relevant to this

litigation. Thus, the Premier Defendants have the right utilize the discovery method of their choice to procure information relevant to this litigation. Most importantly, this is a mass tort situation where Premier is faced with over fifty cases filed by plaintiffs allegedly injured by a product recommended to them by Inspira and its representatives. What's more, Inspira ordered the product from NECC in a similar if not identical fashion and trusted NECC just as Premier did for years.

Inspira argues that the discovery at issue is not “common”. Quite the contrary the collaboration is common to all cases. In addition, there is a need to discovery from Inspira’s point-of-view, with whom Michelle Cassidy discussed this matter, on what occasion and if at all. If this information is already known to the PSC (likely through information gathered at mediation), Premier ought to have knowledge of the information in preparation for trial. For example Joe Alessandrini is a witness that has been identified by Premier but also by Inspira. It is highly likely that either Premier or the PSC can and will call this individual as a witness at the time of trial. His knowledge as the lead pharmacist at Inspira is highly relevant to the claims against all parties in the Inspira cases and those not naming Inspira.

Finally, Inspira goes to great lengths in their brief to illustrate the disconnect between Inspira and Premier. As is illustrated thus far, there is an important connection between Inspira and Premier that must be investigated and is highly relevant to this case.

III. Any Court Order Prohibiting Discovery From Inspira Should Be Modified Or Lifted.

Inspira points out to this Court that Premier has violated a Court Order, which essentially stayed discovery against it while mediation was ongoing and until the conclusion of mediation. What is known to all the litigants in this case is that the above referenced order was not meant to act as a shield from discovery requests by the parties in this case in perpetuity. Inspira has

completed mediation, agreed to terms of settlement with the Trustee and paid \$16million to the Tort Trust in this case. Additionally, the bankruptcy court has approved an injunction against any further claims against Inspira but with a carve-out exception for the remaining litigants in this MDL to pursue comparative fault against the settling parties. (See Dkt No. 1270 to In Re: NECC Bankruptcy Case No. 19882) Additionally, discovery for the purposes of proving Premier's defenses is preserved so long as the discovery is not to pursue any direct claims against the settling defendants in accordance with the settlement terms. (See Dkt No. 1029 to In Re: NECC Bankruptcy Case No. 19882) These terms were carefully carved out with the participation of many of the settling parties, the PSC and the Trustee.

Therefore, to cite now to an order protecting it from discovery during the pendency of mediation is not fulfilling the true intent of the order. Mediation has concluded with Inspira contributing to the settlement funds in this case in exchange for an injunction against future liability. Nothing in either the Chapter 11 Plan, Settlement Agreement or Mediation Order immunizes Inspira from answering document requests, producing fact witnesses or otherwise participating in discovery. The spirit of the Order – disallowing discovery against Inspira so as to focus resources toward resolution – is now moot because Inspira concluded mediation by settling their differences.

In the event that this Court decides that the Order cited to by Inspira has such a preclusive effect, the Premier Defendants now ask that the order be modified and or vacated to allow discovery from Inspira.

IV. **The Deposition Notice Does Not Require Modification, All Topics Are Designed To Lead To The Discovery Of Relevant Information.**

The settling defendants argue for a modification of the 30(b)(6) deposition notice as there is concern that the topics are irrelevant. Discovery is governed by Rule 26 of the Federal Rules of Civil Procedure, which provides in part:

Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action.... It is not ground for objection that the information sought will be inadmissible at the trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.Fed.R.Civ.P. 26(b)(1).

The broad scope of discovery rules and the liberal interpretation given them by the courts demonstrates that Congress realized that a “[m]utual knowledge of all the relevant facts gathered by both parties is essential to proper litigation.” Hickman v. Taylor, 329 U.S. 495, 507–508, 67 S.Ct. 385, 391–392, 91 L.Ed. 451 (1947). While generally, the scope of discovery is broad, it is well recognized that “discovery, like all matters of procedure, has ultimate and necessary boundaries.” Id at 507. Where the material sought is relevant, the burden is on the party seeking non-disclosure or a protective order under Fed.R.Civ.P. 26(c) to show good cause for nondisclosure. Lesal Interiors, Inc. v. Resolution Trust Corp., 153 F.R.D. 552, 561 (D.N.J. 1994).

The moving defendant argues that the information sought by the Premier Defendants is privileged. However, the moving defendant has not cited to one piece of information sought by the Premier Defendants that has been or can be claimed as privileged. In addition, most of if not all of the objections to the requested information goes to the relevancy/admissibility of the documents/testimony. Again, relevancy is not the test for whether information is discoverable, however the information sought is highly relevant to the cases against Premier and likely

admissible. Defendant's Arguments for protective order fail and will be address in the paragraphs below as they have been identified by the moving party:

Topic No. 5: Inspira's policies and procedures for compounding and/or manufacturing pharmaceuticals, ordering pharmaceuticals, ordering compounded pharmaceuticals from compounding pharmacies including but not limited to NECC, maintaining, organizing, labeling, ordering and storing pharmaceuticals including but not limited to compounded medications

The Premier Defendants would like to remind the Court that 21 of the 56 cases pending against Premier and its doctors also named Inspira, but more importantly in those cases the injections were actually, physically performed at Inspira's hospital with NECC's MPA ordered by the hospital. The moving party presumes that not one of these cases will be chosen as a bellwether case. The moving party also asserts that a distinction should be drawn between the cases in which it was originally named and those which it was not. Plain and simple, the cases involving injections at Inspira require an investigation into their own policies, procedures, investigative materials, documents and more in order to prove that Inspira was responsible for choosing and ordering preservative free MPA from NECC.

However, regardless of whether Inspira was named in the suit the practice of ordering medication from NECC is relevant to the diligence put forth by Premier in vetting and ultimately deciding to use NECC for its compounding needs – an issues that is relevant to 100% of Premier's cases and likely admissible.

Topic No. 7 Any and all documentation, correspondence, emails, electronically stored documents, letters, memorandum or other documents relating to or referencing the ordering of Methylprednisolone Acetate from any compounding pharmacy.

The moving defendants make the argument in this section and others that the information sought is irrelevant and not admissible. At this stage of discovery the test for whether information sought is discoverable is whether it is likely to lead to the discovery of relevant information. Speaking on the meaning of “relevancy” in the discovery context, the Supreme Court held that “relevant to the subject matter involved in the pending action”—has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.” Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351, 98 S.Ct. 2380, 2389, 57 L.Ed.2d 253 (1978) (citations omitted). Lesal Interiors, Inc. v. Resolution Trust Corp., 153 F.R.D. 552, 560-61 (D.N.J. 1994)

Here the Premier defendants are inquiring about the ordering of compounded materials from any compounding pharmacy to defend themselves in litigation arising out of the administration of compounded medication that occurred at Inspira’s hospital. Plaintiffs assert that compounded medications are dangerous and not fit for administration to patients. To show that such an assertion is not true, defendants can illustrate that the very hospital that supplied compounded medications to the doctors administering the drugs ordered compounded medications from various pharmacies, over various time periods with little to no known problems – making the injections at Inspira and Premier’s facility reasonable.

Topic No. 8 Any and all documents, correspondence, emails, electronically stored documents, letters memorandum, pictures, drawings, notes or other items produced to the PSC, whether formally or informally.

The Inspira defendants assert that the information produced to the PSC can be obtained by taking the testimony of the plaintiff’s themselves. It is doubtful that the individual plaintiffs have reviewed and/or have knowledge of the information, such that a deposition would yield

information relevant to Topic No. 8. Furthermore, R. 408 is not a bar to the discovery of information especially information regarding settlement negotiations. In fact Courts have declared that F.R.C.P. 26 and F.R.E 408 are in conflict but deserve a resolution in certain instances. The most reasonable means of doing this, and one which best effectuates the aims of both rules, is to require a greater, more “particularized showing” that the evidence sought is relevant and calculated to lead to the discovery of admissible evidence. Lesal Interiors, Inc. v. Resolution Trust Corp., 153 F.R.D. 552, 562 (D.N.J. 1994)

The Premier Defendants want to prove that 1) their efforts in vetting and choosing NECC were adequate and appropriate as was their reliance on Inspira’s Recommendation and years of practice, 2) that the cause of the contamination in this case was not Premier’s conduct or lack thereof, but rather that of NECC and its affiliates and 3) that where injections occurred at Inspira, the hospital bears responsibility for the ordering of the tainted medications. Information disclosed during settlement negotiations is relevant to these proofs. Presumably during negotiations Inspira wished to prove its innocence in order to reduce their indemnity payment. By doing so, information was exchanged to the PSC and likewise from the PSC to Inspira. This exculpatory evidence would play to the benefit of the Premier Defendants’ defenses. Perhaps the PSC has been made aware of information regarding Inspira’s failure to take proper measures in ordering MPA from NECC. Such information is also relevant to the Premier Defense. Finally, should Inspira have provided information about the faulty operations at NECC, helping to prove that the cause of the contamination was through the actions of NECC and its affiliates – that information is highly relevant. The information is highly relevant but more importantly, likely to lead to the discovery of relevant information. Surely the PSC, having access to this information

already will attempt to use it at trial and providing Premier with the opportunity to discover this information now, is appropriate to avoid a trial by ambush.

Topic No. 9 Any and all documents, correspondence, emails, electronically stored documents, letters memorandum, pictures, drawings, notes or other items produced to the department of justice, FBI, FDA or other investigative authority, whether formally or informally.

The only argument advanced here by the moving parties is that the information would not be relevant. For the reasons set forth above and to avoid redundant arguments – Inspira’s requests related to Topic No. 9 should be denied.

Topic No. 11 Any and all policies (written or oral) addressing the administration of Epidural Steroids.

Topic No. 12 Any and all policies (written or oral) addressing the use of, ordering of, storage or, procurement of, or relating in any way to compounded mediation.

To both Topic 11 and 12 Inspira argues against disclosure because of irrelevance an argument already addressed above. It is unclear however whether or not there is actually an objection because the PSC agrees that policies would be relevant to the administration of MPA, however it is highly unusual to think that the Hospital would have a separate policy for epidural steroid injections specific to NECC/MPA. Therefore, policies regarding the administration of steroids should be discussed and disclosed.

Furthermore, policies regarding the ordering of compounded medications is at the heart of this case and involves injections using compounded medications ordered by the hospital. Furthermore, Premier relied on Inspira’s policies for ordering medications in their process of deciding to use NECC for their purposes. In order to prove that Premier was correct in their approach, evidence of Inspira’s correct approach is warranted. Also, in cases where injections

were performed at Inspira, evidence of faulty policies and procedures may be used to assign responsibility to Inspira for the ordering of the contaminated drugs.

Topic No. 13 Any and all efforts, investigation, findings, reports, memoranda, letters, conclusions, impressions, documents, correspondence, site visits, inspections, meetings with NECC or other items related in any way to any investigation performed by Inspira into NECC and its operation.

Just as the policies for ordering medications is relevant to Premier's case so too is any investigation that was done to determine the adequacy of NECC's operations prior to the decision to order from that facility. This category is most important for a jury to consider when deciding between Inspira and Premier as to who was responsible for the contaminated MPA during hospital injections. However, proof of a thorough investigation of NECC may be admissible to prove that Premier's reliance on Inspira's practices and recommendation was adequate and appropriate.

Should it be discovered that an investigation was done, those results would be relevant to show that NECC was an appropriate company with whom to do business. Should it be discovered that an investigation was not done this evidence can be used to show that Inspira (in Inspira injection cases) controlled the ability to do an investigation and chose not to, which can pursued a jury to assign responsibility to the settling defendant. Alternatively, it may be used to show that the standard of care does not require an inspection of a compounding pharmacy before selecting them as a vendor. However, without knowing exactly what the discovery will show, arguing how and when it may be relevant is difficult – yet another reason why the standard for discovery is so broad.

Topic No. 14 Any and all contacts and/or communication either written or oral or electronically or otherwise between Inspira and Premier Orthopedic Associates.

Of course, Premier is interested in communications between Inspira and Premier relevant to the outbreak, ordering from NECC, and anything regarding NECC. It is agreed that a timeframe and further clarification of this topic will be supplied.

Conclusion

For the foregoing reasons the defendant, Inspira Medical Center's motion for protective order should be denied.

Respectfully submitted,

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Dated: 7/16/15

CERTIFICATE OF SERVICE

I, Christopher M. Wolk, hereby certify that this document has been filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants on this date.

Date: July 16, 2015

/s/ Christopher M. Wolk, Esq.